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A DDI ICATION NO	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.	
APPLICATION NO.	FILING DATE				
			EXAMINER		
		l			
			ART UNIT	PAPER NUMBER	
				11	

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

Applicant(s)

08/939,905

Examiner

Ardin Marschel

Gijzen

Group Art Unit 1631



	1 188 18 18 18 18 18 18 18 18 18 18 18 1
Responsive to communication(s) filed on Oct 5, 1999 (Status Request)
Responsive to communication(s) flied on	•
This action is FINAL.	for formal matters, prosecution as to the merits is closed
Since this application is in condition for allowance except in accordance with the practice under Ex parte QuayW83	35 C.D. 11; 453 O.G. 213.
onger, from the mailing date of this community (and the polication to become abandoned. (35 U.S.C. § 133). Extended (Community (Comm	ensions of time may be obtained under the provider
Disposition of Claim	is/are pending in the applicat
X Claim(s) <u>1-29</u>	is/are withdrawn from consideration
Of the above, claim(s)	is/are withdrawn from consideration is/are allowed.
Claim(s)	is/are objected to are subject to restriction or election requirement
Claims	are subject to restriction or election requirement
received. received in Application No. (Series Code/Series received in this national stage application fr	oriority under 35 U.S.C. § 119(a)-(d). pies of the priority documents have been erial Number) From the International Bureau (PCT Rule 17.2(a)).
*Certified copies not received: *Certified copies not received: Acknowledgement is made of a claim for domesting	
Attachment(s) X Notice of References Cited, PTO-892 X Information Disclosure Statement(s), PTO-1449, 4 Interview Summary, PTO-413 Notice of Draftsperson's Patent Drawing Review, Notice of Informal Patent Application, PTO-152	
orr office M	CTION ON THE FOLLOWING PAGES

Serial No. 08/939,905 - 2 - Art Unit: 1631

The art unit designated for this application has changed.

Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Upon reconsideration of the instant application the potential reference that was indicated as being relevant to the examination of this application has recently become unavailable as an issue of concern regarding the instant application. Thus, the suspension, mailed 10/1/98, is hereby withdrawn and

prosecution is hereby resumed. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825 because the sequences which are present in the specification have not been amended to include the corresponding SEQ ID Nos. therewith. For example, sequences are present on pages 25 and 28 but without any SEQ ID Nos. cited therewith. Sequences which come under these rules are also contained in the instant Figures. It is noted, however, that SEQ ID Nos. are not required for such sequences in the Figures, even though the sequence listing must contain the sequences. Applicants are given the same response time regarding this failure to comply as that set forth to respond to this office action.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which

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the claims are directed. The title includes a regulatory region and peroxidase only whereas compositions containing claimed DNA, such as host cells and transgenic plants, as well as methods for peroxidase and gene production are also claimed. It is also noted that although the title includes "peroxidase" that no peroxidase per se is claimed.

Claims 19-29 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for host cell and transgenic plant embodiments, or methods of use thereof, wherein soybean seed coat host cells are present in order to express a coding segment utilizing regulatory region

thereof, wherein soybean seed coat host cells are present in order to express a coding segment utilizing regulatory region within bases 1-1532 of instant SEQ ID NO: 2, does not reasonably provide enablement for any host cell or transgenic or methods of use for expression from the regulatory region 1-1532. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Exparte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature

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of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are

The expression of a coding segment or gene of interest regarding the practice of the instant invention includes the usage of regulatory region bases 1-1532 of instant SEQ ID NO: 2. This region has not been characterized nor found to be capable of expressing a coding segment other than in soybean seed coat cells. The state of regulatory region knowledge yet is insufficient to merely examine the sequence and thus predict what types of host cells would predictably result in expression from such a regulatory region. This unpredictability supports this rejection.

Claims 3, 4, 17, and 25 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for DNA molecules containing at least the regulatory sequence in bases 1-1532 in active form or, alternatively, DNA sequences which have a very high percentage sequence homology over its full length thereby giving it usefulness as a hybridization probe; does not reasonably provide enablement for any substantially

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homologous DNA sequence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in $\underline{\text{Ex}}$ parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in <u>In re Wands</u>, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

Instant claims 3, 4, 17, and 25 are inclusive of any substantially homologous sequence to SEQ ID NO: 2. For these claims, the substantial homology lacks any specific limitation directed to useful embodiments. Claim 3, for example, as presently worded, would include coding sequence for inactive

subject matter which applicant regards as the invention.

Claim 20 is vague and indefinite as to what metes and bounds are meant for the expression of the DNA in the vector which contains "the DNA molecule" of claim 2 via claim 16. The DNA molecule of claim 2 may optionally include only the regulatory

Art Unit: 1631 - 7 -Serial No. 08/939,905 sequence 1-1532 as cited therein. In this option, there is nothing to express. In fact the regulatory sequence itself is generally not expressed but rather a sequence that is downstream from such a regulatory sequence. Thus, the DNA molecule cited in claim 2 would generally only be expressed to the extent of some additional coding segment beyond the regulatory segment. Thus, there generally would never be a complete expression of "the DNA molecule" cited in claim 20 but rather only what it controls as to a gene of interest, for example. Thus, it is confusing as to what is meant in claim 20 wherein apparently there is normally no capability to express the entire DNA molecule therein cited but rather only what is controlled as to expression by the regulatory region given as bases 1-1532. Clarification is requested via clearer claim wording as to what is meant to be expressed in instant claim 20. Claims 28 and 29 also are vague and indefinite as citing the expression of a vector of claim 16 without requiring that the vector contain the gene of interest in said vector. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless --(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent. (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3 and 4 are rejected under 35 U.S.C. § 102(a) as being clearly anticipated by Huangpu et al.

Since the previous office action, mailed 10/1/98, new evidence has been provided in the form of a sequence match between instant SEQ ID NO: 1 and the seed coat peroxidase sequence of Huangpu et al. This match result is given below as follows:

Glycine max seed coat peroxidase isozyme (SPOD4.1) mRNA, partial DEFINITION CDS.

U41657 ACCESSION g1125103 NID

soybean strain=Williams 82Highly. KEYWORDS SOURCE

ORGANISM

Eukaryotae; mitochondrial eukaryotes; Viridiplantae; Glycine max Charophyta/Embryophyta group; Embryophyta; Magnoliophyta; Magnoliopsida; Rutanae; Sapindales; Fabaceae; Papilionoideae; Glycine.

(bases 1 to 1031) REFERENCE

Huangpu, J., Graham, M.C. and Graham, J.S.

Cloning of a soybean cDNA (Accession No. U41657) encoding the AUTHORS abundant anionic seed coat peroxidase (PGR95-136) TITLE

Plant Physiol. 110, 714 (1996) JOURNAL

(bases 1 to 1031) REFERENCE

Huangpu, J., Graham, M.C. and Graham, J.S. AUTHORS

Submitted (30-NOV-1995) John S. Graham, Biological Sciences, Direct Submission Bowling Green State University, Life Sciences Building, Bowling TITLE JOURNAL Green, OH 43403-0212, USA

Location/Qualifiers FEATURES

1. .1031

/organism="Glycine max" source

/strain="Williams 82Highly"

/db_xref="taxon:3847"

1. .852 gene

/gene="SPOD4.1"

<1. .852 CDS

/gene="SPOD4.1"

/EC_number="1.11.1.7"

/note="H202 oxidoreductase"

/codon_start=1

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/product="seed coat peroxidase isozyme" /db_xref="PID:g1125104" /translation="FHDCFVQGCDGSVLLNNTDTIESEQDALPNINSIRGLDVVNDIK TAVENSCPDTVSCADILAIAAEIASVAGRRSGWPVPLGRRDSLTANRTLANQNLPAPF FNLTQLKASFAVQGLNTLDLVTLSGGHTSGRARCSTFINRLYNFSNTGLIHLDTTYLE VLRARCPQNATGDNLTNLDLSTPDQFDNRYYSNLLQLNGLLQSDQERFSTPGADTIPL SIASANQNTFFSNFRVSMIKMGNIGVLTGDEGEIRLQCNFVNGDSFGLASVASKDAKQ KLVAOSK"

291 t 207 g 209 C 324 a BASE COUNT ORIGIN

Length 1031; Score 922; DB 19; 74.1%; 97.9%; Pred. No. 0.00e+00; Query Match 9: Best Local Similarity Indels 12; Gaps 0; Mismatches 10; 1004; Conservative Matches

- 1 TTTCATGATTGCTTTGTTCAAGGTTGTGATGGATCAGTTTTACTGAACAACACTGATACA 60 Db
- 199 TTTCATGATTGCTTTGTTCAAGGTTGTGATGGATCAGTTTTGCTGAACAACACTGATACA 258 QУ
 - 61 ATAGAAAGCGAGCAAGATGCACTTCCAAATATCAACTCAATAAGAGGATTGGACGTTGTC 120 Db
- 259 ATAGAAAGCGAGCAAGATGCACTTCCAAATATCAACTCAATAAGAGGATTGGACGTTGTC 318 QУ
- 121 AATGACATCAAGACAGCGGTGGAAAATAGTTGTCCAGACACAGTTTCTTGTGCTGATATT 180
- 319 AATGACATCAAGACAGCGGTGGAAAATAGTTGTCCAGACACAGTTTCTTGTGCTGATATT 378 Db QУ
- 181 CTTGCTATTGCAGCTGAAATAGCTTCTGTTGCTGGGAGGAGGTC-AGGATGGCCAGTTCC 239 Db
- 379 CTTGCTATTGCAGCTGAAATAGCTTCTGTT-CTGGGAGGAGGTCCAGGATGGCCAGTTCC 437 QУ
- 240 ATTAGGAAGAAGGGACAGCTTAACAGCAAACCGAACCCTTGCAAATCAAAACCTTCCAGC 299
- 438 ATTAGGAAGAAGGGACAGCTTAACAGCAAACCGAACCCTTGCAAATCAAAACCTTCCAGC 497 Db Qу
- 300 ACCTTTCTTCAACCTCAACTTAAAGCTTCCTTTGCTGTTCAAGGTCTCAACACCCT 359 Db
- 498 ACCTTTCTTCAACCTCAACTTAAAGCTTCCTTTGCTGTTCAAGGTCTCAACACCCT 557 QУ

Art Unit: 1631 - 10 -Serial No. 08/939,905 360 TGATTTAGTTACACTCTCAGGTGGTCATACGTCTGGAAGAGCTCGGTGCAGTACATTCAT 419 558 TGATTTAGTTACACTCTCAGGTGGTCATACGTTTGGAAGAGCTCGGTGCAGTACATTCAT 617 Db QУ 420 AAACCGATTATACAACTTCAGCAACACTGGA----CTGATCCA-CT-TGGACACAACATA 473 618 AAACCGATTATACAACTTCAGCAACACTGGAAACCCTGATCCAACTCTGAACACAACATA 677 Db QУ 474 CTTAGAAGTATTGCGTGCAAGATGCCCCCAGAATGCAACTGGGGATAACCTCACCAATTT 533 678 CTTAGAAGTATTGCGTGCAAGATGCCCCCAGAATGCAACTGGGGATAACCTCACCAATTT 737 Db QУ 534 GGACCTGAGCACACCTGATCAATTTGACAACAGATACTACTCCAATCTTCTGCAGCTCAA 593 738 GGACCTGAGCACACCTGATCAATTTGACAACAGATACTACTCCAATCTTCTGCAGCTCAA 797 Db QУ 594 TGGCTTACTTCAGAGTGACCAAGAACGTTTCTCCACTCCTGGTGCTGATACCATTCC-AT 652 798 TGGCTTACTTCAGAGTGACCAAGAACTTTTCTCCACTCCTGGTGCTGATACCATTCCCAT 857 Db QУ 653 TGTCAATAGCTTCAGC-G-AACCAGAATACTTTCTTTTCCAACTTTAGAGTTTCAATGAT 710 858 TGTCAATAGCTTCAGCAGTAACCAGAATACTTTCTTTTCCAACTTTAGAGTTTCAATGAT 917 Db QУ 711 AAAAATGGGTAATATTGGAGTGCTGACTGGGGATGAAGGAGAAATTCGCTTGCAATGTAA 770 918 AAAAATGGGTAATATTGGAGTGCTGACTGGGGATGAAGGAGAAATTCGCTTGCAATGTAA 977 Db QУ 771 TTTTGTGAATGGAGACTCGTTTGGATTAGCTAGTGTGGCGTCCAAAGATGCTAAACAAAA 830 978 TTTTGTGAATGGAGACTCGTTTGGATTAGCTAGTGTGGCGTCCAAAGATGCTAAACAAAA 1037 Db QУ Db QУ

Art Unit: 1631 - 11 -Serial No. 08/939,905 891 TAAAGGCAAATTAGGTTG-AAACCTCTTTGCTAGCTATATTGAAATAAACCAAAGGAGTA 949 1098 TAAAGGCAAATTAGGTTGTAAACCTCTTTGCTAGCTATATTGAAATAAACCAAAGGAGTA 1157 Db Qу 950 GTGTCGATGTCAATTCGATTTTGCCATGTACCTCTTGGAATATTATGTAATAATTATTTG 1009 1158 GTGTGCATGTCAATTCGATTTTGCCATGTACCTCTTGGAATATTATGTAATAATTATTTG 1217 Db QУ 1010 AATCTC 1015 Db 1218 AATCTC 1223 The sequence of the reference is labeled as Db and the majority Qу of the bases in instant SEQ ID NO: 1 is labeled as Qy. Mismatches are shown by the symbol "|" between the sequences. This alignment results in supplying evidence that the peroxidase sequence of the reference matches 1015 bases minus the mismatches of which there are 22. This equals 993 bases that match in the alignment. Instant SEQ ID NO: 1 is 1244 bases long. A 993 base matching sequence is 79.8% sequence matching or homology or sequence identity. It is noted that within the partial, albeit the majority thereof, coding sequence match as given above the matching is 993 bases out of 1015 which is 97.8%. Huangpu et al. disclose the cloning of a partial mRNA into cDNA and discuss certain aspects of the sequencing results as discussed in the citation. It is noted that the instant SEQ ID NO: 2 is longer than instant SEQ ID NO: 1 and is genomic in nature. Thus, for comparing the sequence of the reference to SEQ ID NO: 2 the

percentage sequence match is 993 of 4700 or 21.1%. Although this

is a lesser percentage than the comparison to instant SEQ ID NO:

Art Unit: 1631 - 13 -Serial No. 08/939,905 The Sigma Chemical Company 1990 Catalog discloses several oligomers of oligo(dA) as well as oligo(dT) on page 776. Certain of these oligomers exactly (100%) match segments of instant SEQ ID NO: 2. For example, The Sigma product # 0 5878 is an 8-mer of oligo(dA). Such an 8 base A segment also is present in instant SEQ ID NO: 2 at bases 2682 - 2689. The Sigma product # 0 8753 is a 4-mer of oligo(dC) which is also present in instant SEQ ID NO: 2 at bases 1698 - 1701. Lesser homologies are also present in that Sigma product # O 5878 matches 7 of 8 bases in instant SEQ ID NO: 2 at bases 1418 - 1425 due to one mismatch thus matching at 87.5% which is still deemed substantially homologous. Thus, these oligomers of the Sigma Chemical 1990 Catalog anticipate instant claims 3 and 4. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ... " (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. Miller v. Eagle Mfg. Co., 151 U.S. 186 (1894); In re Ockert, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970). A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101. Claim 1 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of copending application Serial No. 08/723,414. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. The wording of instant claim 1 contains

Art Unit: 1631 - 14 -Serial No. 08/939,905 "comprising" whereas claim 1 of the copending application Serial No. 08/723,414 contains the word "having" in the corresponding location within the respective claims. This rejection is based on the interpretation that "having" and "comprising" are equivalent open claim language terms. It is noted that SEQ ID NO: 1 is the identical in both applications. The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and In re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b). Claims 1-29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of copending application Serial No. 08/723,414. Although the conflicting claims are not identical, they are not patentably distinct from each other because it is noted that instant SEQ ID NO: 2 contains subsequence which is also contained within the smaller SEQ ID NO: 2 of 08/723,414; which is different only in 1341 nucleotides at the 5' end compared to instant SEQ ID NO: 2. This large subsegment in

Art Unit: 1631 - 15 -Serial No. 08/939,905 common between these two sequences results in their sequences being clearly substantially homologous as required in instant claims 3 and 4, as well as subsequences as listed in various instant claims, but not coextensive as to embodiments within their respective scope of subject matter as claimed. The presence of these common embodiments thus supports this obviousness-type double patenting rejection. Instant claim 1 is included in this obviousness-type double patenting rejection due to common embodiments with claims 2 etc. of copending application Serial Number 08/723,414 which are different issues than the above rejection of instant claim 1 under 35 U.S.C. 101 double patenting. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. No claim is allowed. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

- 16 - Art Unit: 1631 Serial No. 08/939,905 Any inquiry of a general nature or relating to the status of this application should be directed to the Technical Center receptionist whose telephone number is (703) 308-0196. September 13, 2000 PRIMARY EXAMINER